EXHIBIT 4

REVIEW OF MEDICAID DRUG STATE PLAN AMENDMENTS

Although there are no statutory provisions for payment rates for Medicaid drugs, states are required to set rates in accordance with regulations at 42 CFR 447.301-333.

BACKGROUND

Estimated Acquisition Cost (EAC) and Dispensing Fee

There are two components of this payment rate and each is required to be determined separately. The first is EAC, which simply means the cost to the pharmacy of obtaining the drug. The second is the dispensing fee, which is the pharmacy's direct and indirect cost of dispensing a drug. This includes everything from packaging to pharmacy overhead costs such as the electricity and salaries. Each component is measured separately. The ingredient cost is defined in 42 CFR 447.301 as the state "...agency's best estimate of the price generally and currently paid by providers for a drug marketed or sold by a particular manufacturer or labeler in the package size most frequently purchased by providers." Dispensing fees are simply required to be "reasonable". The regulations require that the agency's payment methodology for prescription drugs be described "comprehensively" in the state plan.

In practice we have told states that wish to modify their EAC levels that they must provide a factual basis to support a change in the EAC or dispensing fee. One method to support a change in EAC is to audit an appropriate number of pharmacies to determine current acquisition costs.[1] We have told the CMS Regional Offices (RO) that in reviewing state plan amendments (SPAs), they should compare rates for contiguous states rates as well as other states in the region. We have also said that they should consider drug cost studies. For the dispensing fee, we have said states could establish a reasonable fee by: (1) audits and surveys of operational costs; (2) compilation of data regarding professional salaries and fees; and (3) analysis of compiled data regarding pharmacy overhead costs, profits, etc. For dispensing fees, we have told the regional offices that they could, among other things, compare the proposed change to the related price indices, e.g. the Consumer Price Index (CPI).

Office of Inspector General (OIG) Reports and State Submitted Audits

Recently issued OIG reports indicated that the actual acquisition cost of brand name prescription drug products nationally is an average of AWP less 21.84 percent. Recent discussions with the OIG indicate that they will further refine this number to differentiate it between those single source (brand name drugs) without generic competition and those with innovator multiple source (brand name drugs) with generic competition. The OIG indicates that the single source drugs will likely show an average discount of around 17% and the innovator multiple source drugs of around 24%. The OIG also studied generic

[1] States usually base the EAC on Average Wholesale Price (AWP) levels with a significant discount e.g. AWP less 10%.

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drug discounts and found that the actual acquisition cost of generic prescription drug products nationally is an average of AWP less 65.93 percent.

State studies vary on the level of discount and while an exact level of discount cannot be determined, they appear to average in the range of 20% to 35% off of AWP.

ANALYSIS

In recent months there has been an increase in SPAs proposing to change the reimbursement methodology (a listing of these SPAs is attached). Where there are surveys of costs, the findings generally show that these State's reimbursement could have been reduced by a percentage greater than the proposed AWP discount levels. The lesser level of discount is generally the result of negotiations that occur between the state and pharmacy representatives after the survey results are known. In other cases, the states legislature have responded to the escalating costs of Medicaid drugs by enacting legislation that increases the discount in the ingredient cost or the dispensing fee of these drugs. Legislation usually does not address why these rates are the best estimates or are reasonable.

It is proving increasingly difficult to require the states to establish payment rates in adherence to regulatory requirements. Accordingly, we believe an analysis and an acceptance of other factors states are now using to establish payment rates should be considered in looking at the EAC and the dispensing fee.

We think that the first part of our review should be continuing to rely on the existing review criteria (i.e. survey and rates in other states). For EAC, we would continue to look to surrounding states or because we now think that payment rates vary little nationwide, to a nationwide average. We think it is also helpful to strongly consider approval where the direction of the state's proposed level of reimbursement represents a program savings that does not appear to affect pharmacy participation. Finally, we think EAC needs to include a broader measure of factors that would result in a state agency's best estimate. We could consider the actions of the legislature or negotiations that result in a lower payment rate, even if that rate may differ from other documentation, such as a state survey.

Because the requirements to set dispensing fees are less specific, we would continue to allow states greater flexibility here. For instance, we would permit states to reduce these fees not only to reflect lower costs; but also to permit states to increase them to encourage other program savings measure, such as allowing a higher dispensing fee for the use of generic drugs.

Apart from that, we think a longer-range look at the OIG and state studies as well as a reevaluation of current regulations are in order. If, in fact, there needs to be another basis, such as nationwide surveys that can establish these rates, we need to look at the feasibility and impact of doing so.

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OPTIONS

(The following options are for approvals of SPAs, denials would be determined on a case-by-case basis)

For ingredient costs –

Approve SPAs that **decrease** the ingredient cost as long as it is no lower than that of another state, which has not experienced a significant decline in pharmacies (proxy measure for access).

Approve SPAs that **decrease** the ingredient cost as long as it is no lower than the levels of costs found by the OIG (i.e., approximately 17 % for single source, 24% for innovator multiple source, and 65.93 % for generics).

Approve SPAs to **increase** payment for ingredient costs if they are less than the median nationally.

Approve any rates set in state statute.

For dispensing fees –

Approve SPAs with higher dispensing fees for generics.

Approve SPAs with dispensing fees **increases** when the proposed fee is less than the national median.

Approve SPAs with dispensing fee **decreases** when the proposed fee is no less than what is paid by any other state (proxy measure for access).

RECOMMENDATIONS

We recommend that we implement all of the above options. On SPAs that did not meet the above criteria, we would not automatically disapprove that SPA. We would look at the individual circumstances in the state as well as its supporting documentation and rational to decided whether to approve the SPA.

DECISION

Approve ____________________ ________ Disapprove____________________ ________
Signature Date Signature Date

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